United States Court of Federal Claims

No. 14-790 V
Filed Under Seal: December 21, 2017
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MICHAEL MCCOLLUM, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	)	Vaccine case; Motion for Review; Influenza Vaccine; Standard of Review; *Althen*; Burden of Proof; Motion for Review denied.

OPINION

Richard Gage, Richard Gage, P.C., Cheyenne, WY, for petitioners.

Alexis B. Babcock, Vaccine/Torts Branch, Civil Division, United States Department of Justice, Washington, DC, for respondent.

SMITH, Senior Judge:

Petitioner, Michael McCollum, seeks review of a decision issued by Special Master Brian H. Corcoran denying his petition for vaccine injury compensation. Petitioner brought this action pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-10 et seq. (2012), alleging that petitioner developed narcolepsy with cataplexy as a result of his receiving the influenza vaccine in the fall of 2011. The Special Master denied compensation, finding that petitioner's narcolepsy with cataplexy was not caused by the vaccination. *McCollum v. Sec'y of Health & Human Servs.*, 2017 WL 5386613 (Fed. Cl. Spec. Mstr. Sept. 15, 2017) (*McCollum*). Petitioner now moves for review of this decision. For the reasons that follow, the Court **DENIES** his motion.

[1] An unredacted version of this opinion was issued under seal on December 21, 2017. The parties were given an opportunity to propose redactions, but no such proposals were made.

I. BACKGROUND

A brief recitation of the facts provides necessary context.[2]

Mr. McCollum's medical history contains several pre-existing health conditions related to the narcolepsy[3] with cataplexy[4] he alleges resulted from the influenza[5] vaccine. These health conditions include, but are not limited to, obstructive sleep apnea ("OSA"),[6] smoking, attention deficit/hyperactivity disorder, obesity,[7] type II diabetes,[8] severe hypertension,[9] and chronic back problems. The records obtained from Dr. Joseph C. Petrini, petitioner's primary care physician, include several documented incidents of general sleep related issues that predate the alleged influenza vaccination. The incidents occurred sporadically from October 2009 to July 2011, and they were typically referred to in general terms, such as "sleep disturbance," "difficulty sleeping," "sleep problems," "sleepiness," and "still too fatigued to work."

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[2] As the basic facts here have not changed significantly, the Court's recitation of the background facts here draws from the Special Master's earlier opinion in *McCollum*.

[3] Narcolepsy is defined as "recurrent, uncontrollable, brief episodes of sleep, often associated with hypnagogic or hypnopompic hallucinations, cataplexy, and sleep paralysis." *Dorland's Illustrated Medical Dictionary* at 1232 (32nd ed. 2012) ("*Dorland's*").

[4] Cataplexy is defined as "a condition in which there are abrupt attacks of muscular weakness and hypotonia triggered by an emotional stimulus such as mirth, anger, fear, or surprise. It is often associated with narcolepsy." *Dorland's* at 303.

[5] Influenza is defined as "an acute viral infection of the respiratory tract that may occur in isolated cases, in epidemics, or in pandemics. . . . It is marked by inflammation of the nasal mucosa, pharynx, and conjunctival; headache; myalgia; often fever, chills, and prostration; and occasionally involvement of the myocardium or central nervous system." *Dorland's* at 937.

[6] Sleep apnea is defined as "transient periods of cessation of breathing during sleep. It may result in hypoxemia and vasoconstriction of pulmonary arterioles, producing pulmonary arterial hypertension." Obstructive sleep apnea is defined as "sleep apnea resulting from collapse or obstruction of the airway with the inhibition of muscle tone that occurs during REM sleep." *Dorland's* at 117.

[7] Obesity is defined as "an increase in body weight beyond the limitation of skeletal and physical requirement, as the result of an excessive accumulation of fat in the body." *Dorland's* at 1309.

[8] Type II diabetes is defined as "one of the two major types of diabetes mellitus, characterized by peak age of onset between 50 and 60 years, gradual onset with few symptoms of metabolic disturbance, and no need for exogenous insulin." *Dorland's* at 506.

[9] Hypertension is defined as "high arterial blood pressure." *Dorland's* at 896.

In addition to preexisting sleep related issues, petitioner also experienced a number of other medical issues similar to those complained of after the alleged vaccination. For example, on July 10, 2010, petitioner was hospitalized for "an altered level of consciousness with difficulty expressing himself and bilateral shaking of his arms," at which point Mr. McCollum reported that he fell asleep while riding in a car and "developed speech disturbance" earlier in the day. Petitioner received an electroencephalogram ("EEG")[10] and an echocardiogram,[11] both of which showed normal results. The consulting neurologist, Dr. Gerald Wahl, concluded that the petitioner's clinical presentation was indicative of a transient ischemic attack ("TIA"),[12] but that the TIA could not account for bilateral arm shaking. The record next indicates a similar occurrence after Mr. McCollum received his alleged influenza vaccination.

Petitioner was unable to provide direct proof establishing that he actually received the influenza vaccine in October of 2011, instead attempting to prove that he received the vaccine through circumstantial evidence. In doing so, petitioner relies on facts involving third parties. Petitioner alleges that his wife, Linda McCollum, was admitted to Salinas Memorial emergency room on September 24, 2011. Upon discharge, his wife received the influenza vaccine and was advised that her family should follow suit. Mrs. McCollum asserts that she then told her husband that he needed the vaccine, and petitioner claims he did so a few weeks later. Mr. McCollum then alleges that he received the influenza vaccine from a Walgreens pharmacy near his home around October 5, 2011. The Walgreens Company could not provide a record of the vaccination, but was able to confirm that the H1N1[13] vaccine was being administered at stores across the United States in the fall of 2011, and that the cost of the vaccination was $31.99 for uninsured patients. Petitioner filed bank records for September and October 2011, which revealed that the only purchase dated after Mrs. McCollum's hospitalization that matched or surpassed the cost of the vaccine in 2011 occurred on October 18, 2011.

Although Mr. McCollum's medical records do not include any reference to possible early signs of narcolepsy in the months immediately after the alleged vaccine, petitioner argues that he was experiencing symptoms. At the hearing before the Special Master, he testified that the symptoms began around December 2011, when he "would just drop [into sleep] like a stone." He also alleged that he would hallucinate while driving on the freeway and he would sit in front of the television and suddenly wake up and realize he had dropped the cup that had been in his

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[10] An EEG is defined as "a recording of the potentials on the skull generated by currents emanating spontaneously from nerve cells in the brain." *Dorland's* at 600.

[11] Echocardiography is defined as "a method of graphically recording the position and motion of the heart walls or the internal structures of the heart and neighboring tissue by the echo obtained from beams of ultrasonic waves directed through the chest wall." *Dorland's* at 589.

[12] A TIA is defined as "a brief attack of cerebral dysfunction of vascular origin, with no persistent neurological deficit." *Dorland's* at 178.

[13] H1N1 (otherwise known as "swine flu") is defined as "an acute, highly contagious, respiratory disease of hogs caused by a species of Influenzavirus A." *Dorland's* at 937.

hand. Petitioner's wife testified that petitioner began having symptoms of cataplexy in January of 2012, and that petitioner felt cataplexy when he would become animated by telling jokes, playing with his granddaughter, or when he received praise.

Petitioner visited the Community Hospital of the Monterey Peninsula emergency room on January 29, 2012, complaining of weakness in his left leg, tingling on the left side of his face, lightheadedness, and dizziness. His neurological examination and TIA workup were both normal, and the treating physician concluded that petitioner's sedative medications, Sorma and Norco, which had previously been prescribed for his back pain, had likely contributed to his symptoms. On January 30, 2012, petitioner visited Dr. Petrini, who indicated that his symptoms could be neurological, and referred him to neurologist, Dr. Wayne Shen. Petitioner visited Dr. Shen on February 7, 2012, at which point he reported that he was experiencing double vision, hallucinations, the sudden onset of sleep on long drives, weakness and numbness in his leg, and that he would get "a weird feeling on his face" when he laughed. He also complained of constant sleepiness, increased sleeping generally, and sleep paralysis. Dr. Shen proposed several differential diagnoses, including narcolepsy, and ordered a Multiple Sleep Latency Test ("MSLT").

Petitioner alleges that his cataplexy worsened by mid-February. He returned to Dr. Shen on March 1, 2012, reporting worsening symptoms, including "[s]leep dreaming and waking up." At that point the MSLT results came back, Dr. Shen indicated that a diagnosis of narcolepsy with "near cataplexy" was appropriate, and Dr. Shen referred petitioner to Dr. June Seliber-Klein, a neurologist/sleep specialist at the June Klein Practice in Monterey, California, for further evaluation. Mr. McCollum had an initial evaluation with Dr. Klein on April 16, 2012, but, as Mr. McCollum never returned for a follow-up visit, those records are inconclusive.

On June 20, 2012, petitioner visited the Stanford Sleep Medicine Clinic and was seen by Drs. Vikas Jain and Emmanual Mignot. They conducted a diagnostic polysomnogram,[14] and diagnosed petitioner with "hypersomnia[15] with sleep apnea (unspecified)," which is a condition characterized by excessive daytime sleepiness but distinct from narcolepsy. The doctors then took a blood sample to test for the Human Leucocyte Antigen,[16] a gene that predisposes individuals to narcolepsy, but which is also common in the general population without narcolepsy. Mr. McCollum tested positive for the gene, and the doctors ultimately revised his

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[14] Polysomnography is defined as "the polygraphic recording during sleep of multiple physiologic variables, both directly and indirectly related to the state and stages of sleep, to assess possible biological causes of sleep disorders." *Dorland's* at 1494.

[15] Hypersomnia is defined as "excessive sleeping or sleepiness, as in any of a group of sleep disorders with a variety of physical and psychogenic causes." *Dorland's* at 896.

[16] The Human Leucocyte Antigen is defined as "histocompatibility antigens governed by genes of the HLA complex, a region on the short arm of chromosome 6 containing several genetic loci, each having multiple alleles." *Dorland's* at 105.

diagnosis to include narcolepsy and cataplexy after he completed a sleep study, during which he exhibited hypoventilation,[17] low oxygen saturations,[18] and OSA.

Petitioner continued to participate in sleep studies and visit the Stanford Sleep Medicine Clinic from August 2012 through April 2013. He was heavily medicated to counteract his symptoms, but continued to report "rather significant cataplexy." His medication was eventually increased and he was able to return to work on May 10, 2013.

Petitioner filed his vaccine petition on August 29, 2014, pursuant to the Vaccine Act. Petitioner filed the expert report and curriculum vitae of Dr. Marcel Kinsbourne,[19] a neurologist, on September 15, 2015. Respondent filed an expert report from Dr. Maryanne Deak,[20] who specializes in sleep disorders, on June 13, 2016. An entitlement hearing was held in Washington, DC on April 4, 2017. On September 15, 2017, Special Master Corcoran issued a

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[17] Hypoventilation is defined as "a state in which there is a reduced amount of air entering the pulmonary alveoli, resulting in increased carbon dioxide tension." *Dorland's* at 908.

[18] Oxygen saturations are defined as "a measure of the degree to which oxygen is bound to the hemoglobin, usually measured by a pulse oximeter, given as a percentage calculated by dividing the maximum oxygen capacity into the actual oxygen content and multiplying by 100." *Dorland's* at 1670.

[19] Dr. Kinsbourne received his medical degree in England, has been licensed to practice medicine in North Carolina since 1967, and is board-certified in pediatrics. *See* Dr. Kinsbourne Curriculum Vitae, Ex. 14 (ECF No. 21) (hereinafter "Kinsbourne CV"), at 1. From 1967 to 1974, Dr. Kinsbourne served as an associate professor in pediatrics and neurology and as a senior research associate at Duke University Medical Center. *Id*. at 2. He then held a series of academic positions. *Id*. His clinical experience includes serving as a senior staff physician in Ontario from 1974-1980, and serving as a clinical associate in neurology at Massachusetts General Hospital from 1981-1991. *Id*. He does not have any specific expertise in narcolepsy, nor has he studied or researched in immunologic issues raised by theories claiming vaccine causation.

[20] Dr. Deak graduated from Georgetown University School of Medicine in 2004, and she is a board-certified neurologist and sleep specialist currently employed at eviCore healthcare, where she works on guideline development and clinical case review for sleep medicine or neurology cases. *See generally* Dr. Deak Curriculum Vitae, Ex. B (ECF No. 32) (hereinafter "Deak CV"); Transcript of Proceedings (hereinafter "Tr.") at 130-32. Dr. Deak completed residencies at both New York University and University of Massachusetts. Deak CV at 1. She served as a clinical and research fellow in sleep medicine at Brigham and Women's Hospital at Harvard Medical School. *Id*. She then became an instructor at the same hospital in the Division of Sleep Medicine in the Department of Internal Medicine. *Id*. She often works with patients being evaluated for narcolepsy, and she has helped develop a stimulant medicine for patients with narcolepsy and central hypersomnia. *Id*. at 8. She has written or coauthored several peer reviewed articles and book chapters in the area of sleep disorders. *Id*. at 8-10.

decision denying petitioner's claim and finding that petitioner was not entitled to compensation because he failed to establish a reliable causation theory.

On October 5, 2017, petitioner filed a Motion for Reconsideration, alleging that a new "retrospective review[21] from 20 premiere pediatric sleep centers in the United States. . .found 'a significant increase in the number of childhood narcolepsy cases with seasonal pattern after the 2009 H1N1 pandemics in the United States.'" Petitioner's Motion for Reconsideration at 1; *see also* Simakajornboon, et al. On October 12, 2017, Special Master Corcoran denied petitioner's Motion for Review, finding that the abstract review petitioner provided "says too little about [the H1N1 vaccine's association with narcolepsy] for me to conclude that it changes the balance of evidence in Petitioner's favor." Order Denying Motion for Reconsideration at 5.

On October 16, 2017, petitioner filed his Motion for Review (hereinafter "MFR") of the Special Master's decision. Respondent filed a response to petitioner's Motion for Review (hereinafter "Resp. to MFR") on November 15, 2017. The Court held Oral Argument on December 19, 2017, and the Motion for Review is now ripe for decision.

II. DISCUSSION

Under the Vaccine Act, this Court may review a special master's decision upon the timely request of either party. *See* 42 U.S.C. § 300aa-12(e)(1)-(2). In that instance, the Court may: "(A) uphold the findings of fact and conclusions of law. . ., (B) set aside any findings of fact or conclusion of law. . .found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. . ., or, (C) remand the petition to the special master for further action in accordance with the court's direction." *Id*. at § 300aa-12(e)(2)(A)-(C). Findings of fact and discretionary rulings are reviewed under an "arbitrary and capricious" standard, while legal conclusions are reviewed *de novo*. *Munn v. Sec'y of Health & Human Servs.*, 970 F.2d 863, 870 n. 10 (Fed. Cir. 1992); *see also Doyle ex rel. Doyle v. Sec'y of Health & Human Servs.*, 92 Fed. Cl. 1, 5 (2010).

Althen v. Secretary of Health & Human Services provides the evidentiary burden for petitioners attempting to succeed in a vaccine petition based on causation. *See generally Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005). In order to prove causation-in-fact, a petitioner must

> show by preponderant evidence that the vaccination brought about [petitioner's] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination

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[21] M. Simakajornboon, et al., *Increased Cases of Childhood Narcolepsy After the 2009 H1N1 Pandemics: Preliminary Data from the Pediatric Working Group of the Sleep Research Network*, 40 Sleep A337 (2017) (hereinafter "Simakajornboon, et al.").

> was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Id. at 1278. In order to succeed, petitioners must provide a "reputable medical or scientific explanation" for their claim. *Id.*

Within this framework, petitioner makes two numbered objections to the September 15, 2017 decision. *See* MFR at 1. First, petitioner asserts that the Special Master acted arbitrarily in ignoring evidence of a challenge-rechallenge in Petitioner. *Id*. Second, petitioner argues that the Special Master erred as a matter of law by increasing Petitioner's burden of proof supporting a medically-plausible theory of causation in support of *Althen* prong one. *Id.*

A. Challenge-Rechallenge

In his Motion for Review, petitioner alleges that the Special Master acted arbitrarily in ignoring evidence of petitioner's challenge-rechallenge response. MFR at 16. A challenge-rechallenge occurs "when a patient who had an adverse reaction to a vaccine suffers worsened symptoms after an additional injection of the vaccine." *Capizzano v. Sec'y of Health and Human Servs.*, 440 F.3d 1317, 1322 (Fed. Cir. 2006). In making this argument, petitioner alleges that, because his symptoms worsened after receiving an alleged second vaccination, the Special Master should have considered that to be "unassailable evidence that the vaccine **did**, in fact, cause the injury at issue." *Id.* (emphasis in original). This Court does not agree with petitioner's argument.

As an initial matter, petitioner has failed to provide any direct evidence he ever received the initial vaccine at issue, let alone the second vaccine which would have triggered the challenge-rechallenge response. The Special Master appears to accept petitioner's evidence, which is circumstantial at best, as proof that petitioner actually received the influenza vaccine in October of 2011. Mr. and Mrs. McCollum both testified that petitioner received a second influenza vaccination in October of 2012 while undergoing treatment at the Stanford Sleep Medicine Clinic. The Special Master acknowledged this by stating in his decision that petitioner testified that "his physicians requested (contrary to the theory proposed herein relating the vaccine to the claimed illness) that he receive an *additional* flu shot, and that he did so in October 2012, although (like the vaccination at issue in this case) there is no formal record of it." Decision Denying Entitlement (hereinafter "Dec.") at 8 (emphasis in original). As there is no direct evidence that the second vaccine was ever received, petitioner's argument that "[t]he evidence regarding the second vaccination is clear and unrebutted," is misleading and uncorroborated. Even if there was evidence in the record of the second vaccine, the medical records from the Stanford Sleep Medicine Clinic did not attach any significance to the petitioner's alleged increase in vivid dreams that purportedly occurred following the second vaccine. *See* Petitioner's Exhibit (hereinafter "Pet. Ex.") 6 at 116-19.

Secondly, petitioner is attempting to argue that the Special Master should have considered the challenge-rechallenge response as proof that the purported influenza vaccine

caused his narcolepsy, despite the fact that petitioner never made any challenge-rechallenge argument in the proceedings below. Vaccine Rule 8(f) provides that "[a]ny fact or argument not raised specifically in the record before the special master will be considered waived and cannot be raised by either party on review of the special master's decision." Rules of the Court of Federal Claims (hereinafter "RCFC"), Appendix B, Rule 8(f). Petitioner never raised the challenge-rechallenge issue during the proceedings before the Special Master, either in the expert testimony or during trial testimony. *See generally* Pet. Ex. 13, 41. The Special Master cannot be expected to, *sua sponte*, apply a legal theory that petitioner did not himself raise. To ask the Special Master do so would be to shift the burden of proof from the petitioner to the Special Master himself. As such, petitioner's challenge-rechallenge issue has been waived.

In addition to asserting that the Special Master's actions were arbitrary, petitioner asks this Court to forego a remand as petitioner believes "[t]he evidence on this point is explicit enough to justify this Court reach an independent conclusion that petitioner has presented sufficient proof of liability and is entitled to compensation." MFR at 18. Findings of fact and discretionary rulings are reviewed under an "arbitrary and capricious" standard. *Munn*, 970 F.2d at 870 n.10; *see also Doyle ex rel. Doyle*, 92 Fed. Cl. at 5. This Court will not presume to review this case, *de novo*, in order to make unsupportable findings of fact that further a legal theory that was previously waived by petitioner.

B. *Althen* Prong One

In addition to arguing that the Special Master ignored evidence of a challenge-rechallenge response, petitioner also asserts that the Special Master erred as a matter of law by increasing petitioner's burden of proof supporting a medically plausible theory of causation in support of *Althen* prong one. Petitioner concludes his argument by stating that he has provided "a *medically plausible theory*, accepted by top researchers in the field, and therefore, [has satisfied] *Althen* prong one." MFR at 24 (emphasis added). Essentially, petitioner is asking this Court to set aside Federal Circuit precedent in favor of the less stringent standard as set forth in *Contreras v. Sec'y of Health & Human Servs.* 121 Fed. Cl. 230, 245 (2015). This Court rejects the application of the *Contreras* standard in this case.

This Court is constrained by the Federal Circuit's decision in *Moberly v. Sec'y of Health & Human Servs*, which held that "[a]lthough a Vaccine Act claimant is not required to present proof of causation to the level of scientific certainty, the special master is entitled to require some indicia of reliability to support the assertion of the expert witness." 592 F.3d 1315, 1324 (Fed. Cir. 2010). *Althen* requires that petitioners must provide a "reputable medical or scientific explanation" for their claim. *Althen*, 418 F.3d at 1278. "The determination of whether a proffered theory of causation is 'reputable' may 'involve an assessment of the relevant scientific data.'" *Hazlehurst ex rel. Hazlehurst v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 473, 479 (2009) (quoting *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009)). Furthermore, "'reversible error will be extremely difficult to demonstrate' where the special master 'has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision.'" *Porter v. Sec'y of Health & Human Servs.*,

663F.3d 1242, 1253-54 (quoting *Hines v. Sec'y of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991)); *see also Lombardi v. Sec'y of Health & Human Servs.*, 656 F.3d at 1343, 1353 (Fed. Cir. 2010). Such is the case here.

Here, the Special Master evaluated the petitioner's medical records in conjunction with the expert reports and testimony and found that petitioner had not met his burden under *Althen* prong one. Petitioner argues that "the study from China[22] has been considered sufficiently reliable by experts in the field to prompt the investment of considerable resources into related research." MFR at 21. He also asserts that "world class researchers. . .have readily accepted the Chinese study as evidence of a link between H1N1 virus and narcolespy [*sic*]." *Id*. at 20. Petitioner further cites to a study[23] on the association between the influenza vaccine, Pandemrix, and narcolepsy as probative of a causal link between the two. *Id*. at 21.

As the Special Master pointed out, "[t]here is an immediate facial limitation, however, to the application of such literature to this case. Pandemrix is not a form of the flu vaccine administered in the U.S."[24] Dec. at 11 (emphasis in original). Petitioner's legal theory is belied in three ways. First, the studies provided deal with the adjuvanted[25] monovalent[26] version of the H1N1 vaccine, while the vaccine administered in the United States was unadjuvanted. Second, a subsequent article[27] of a similarly-adjuvanted vaccine in Canada observed no similar association between the adjuvanted vaccine and narcolepsy, which suggests the correlation may be specific to Pandemrix. Third, to date, there is no evidence that the vaccine administered in the United States is liked to an increased risk of narcolepsy, and, in fact, the only epidemiological study[28]

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[22] Fang Han, et al., Narcolepsy Onset is Seasonal and Increased Following the 2009 H1N1 Pandemic in China, 70 Am. Neurological Ass'n 410, 410-17 (2011).

[23] Elizabeth Miller, et al., Risk of Narcolepsy in Children and Yong People Receiving AS03 Adjuvanted Pandemic A/H1N1 Influenza Vaccine: Retrospective Analysis, Brit. Med. 346, 794 (2014).

[24] *Narcolepsy Following Pandemrix Influenza Vaccination in Europe*, CDC, https://www.cdc.gov/vaccinesafety/concerns/history/narcolepsy-flu.html (last visited December 20, 2017).

[25] Adjuvant is defined as "assisting or aiding; a substance that aids another, such as an auxiliary remedy; in immunology, a nonspecific stimulator of the immune response." *Dorland's* at 32.

[26] Monovalent is defined as "having a valence of one; denoting an antiserum, vaccine, or antitoxin specific for a single antigen or organism." *Dorland's* at 1179.

[27] S. Sohail Ahmed, et al., *Narcolepsy, 2009 A(H1N1) Pandemic Influenza, and Pandemic Influenza Vaccinations: What is Known and Unknown About the Neurological Disorder, the Role for Autoimmunity, and Vaccine Adjuvants*, 50 J. Autoimmunity 1, 7 (2014).

[28] Johnathan Duffy, et al., *Narcolepsy and Influenza A (H1N1) Pandemic 2009 Vaccination in the United States*, 83 Neurology 1823, 1823-30 (2014).

that dealt with the H1N1 vaccine in the United States found that there was no causal connection between the vaccine and narcolepsy. The Special Master clearly considered the expert reports and testimony proffered by both the petitioner and the respondent, and he came to the conclusion that petitioner failed to provide a "'reputable medical or scientific explanation' for [his] claim." *See Althen*, 418 F.3d at 1278; *see generally* Dec. at 8-15. The Special Master has clearly "considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision." *Hines*, 940 F.2d at 1528. As such, he in no way elevated petitioner's burden of proof in regard to *Althen* prong one.

III. CONCLUSION

This Court finds that petitioner has not met his burden of proof in alleging that his influenza vaccine resulted in his narcolepsy and cataplexy. For the foregoing reasons, the Court **DENIES** petitioner's Motion for Review.[29]

IT IS SO ORDERED.

s/ *Loren A. Smith*
Loren A. Smith,
Senior Judge

[29] This opinion shall be unsealed, as issued, after January 4, 2018, unless the parties, pursuant to Vaccine Rule 18(b), identify protected and/or privileged materials subject to redaction prior to that date. Said materials shall be identified with specificity, both in terms of the language to be redacted and the reasons therefor.